FEB 2 7 2013

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Vital Sync™ System.

A.1. Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	February 14, 2013
Contact Person:	Kelsey Lee Senior Regulatory Affairs Specialist (303) 305-2760
A.2. Proprietary Name:	**Vital Sync™ System, Model 5000**
Common Name:	Cardiac Monitor (without alarms)
Device Classification Regulation:	21 CFR 870.2300 – Class II
Device Product Code & Panel:	MWI: Monitor, Physiological, Patient (without arrhythmia detection or alarms) Cardiovascular
A.3. Predicate Device:	**Vital Sync™ System (K093244)**

A.4. Device Description

The Vital Sync™ System is being extended to offer additional device compatibility and parameter display.

The design features of the subject Vital Sync™ System are substantially equivalent to the design features of the predicate Vital Sync™ system.

A.5. Intended Use

The subject Vital Sync™ System has the same indications for use as the predicate Vital Sync™ System. The only difference is the addition of displayed parameters in the subject Vital Sync™ System and the devices that are compatible.

The Indications for use are as follows:
The Vital Sync™ System is intended for the display and recording of multiple physiological parameters of adult, pediatric and neonatal patients. It is not intended for alarm notification, nor is it intended to control any of the independent bedside devices it is connected to. A listing of supported devices and displayed parameters is attached.

WARNING: The Vital™ Sync System is not an active patient monitoring system. It is intended to supplement and not replace any part of the hospital's device monitoring

A.6. Technological Characteristics Comparison

The subject Vital Sync™ System and the legally marketed predicate Vital Sync™ System have identical indications for use and similar displayed parameters and device compatibility, have the same principles of operation, and utilize the same hardware.

The subject Vital Sync™ System includes additional device compatibility and additional parameter display.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through driver validation and regression testing. The driver validation and regression tests were run to show that the data collected from the bedside devices was not being corrupted and would be shown accurately on the subject device. The results of the tests show that the subject Vital Sync™ System is substantially equivalent to the legally marketed predicate Vital Sync™ System.

B.2. Substantial Equivalence – Clinical Evidence

N/A – Clinical evidence was not necessary to show substantial equivalence

B.3. Substantial Equivalence – Conclusions

Substantial equivalence is shown through driver validation and regression testing. The indications for use, intended population, hardware utilized and principles of operation are identical between the subject and predicate. The subject and predicate differ in that the subject is capable of additional device compatibility and displaying additional parameters. No new questions of safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject device can be expected to perform at least as well as the predicate.

Displayed Parameters

Amplitude Integrated EEG Left
Amplitude Integrated EEG Right
Anesthetic Agent
Air Temperature
Air Temperature Setting
Airway Temperature
Arterial Base Excess
Arterial Bicarbonate
Arterial pH
Arterial Temperature
Average Heart Rate
Axillary Temp
Bi-level Positive Airway Pressure
BIS
Bladder Temperature
Blood Temperature/Pulm. Artery Temperature
Body Surface Area
Bolus Cardiac Output
Bolus Cardiac Index
Brain PO2
Brain Temp
Calculated SO2
Cardiac Index
Cardiac Output
Stat Cardiac Index
Stat Cardiac Output
Cardioplegia Line Pressure
Central Venous Pressure
Cerebral Perfusion Pressure
Cerebral Blood Flow
Ch1 rSO2
Ch2 rSO2
Ch3 rSO2
Contractility Index
Continuous Cardiac Index
Continuous Cardiac Output
Control Temp
Core Temperature
Coronary Sinus Pressure
Continuous Positive Airway Pressure
Delta Pressure
Dynamic Compliance
End Diastolic Volume Index
Stat End Diastolic Volume
Stat End Diastolic Volume Index
Exhaled Minute Volume
End Inspiratory Pressure
End Systolic Volume
End Systolic Volume Index
End Tidal CO2
Environment Temperature
Esophageal Temperature
Exhaled Tidal Volume
Exhalation Time
Expired Positive Airway Pressure
Inspired Fraction of Oxygen
Infusate Temp
Flow Rate 1
Flow Rate 2
Flow Rate 3
Gastric pCO2
Heart Rate
Heater Output Percent
Heater Output Percent Setting
Hematocrit
Hemoglobin
High Inspired Pressure Setting
Humidity
Humidity Setting
Variation of Contractility Index
Inspired : Expired Ratio
Inspired CO2
Inspired O2 Setting
Insp Pos Air Pressure
Inspiratory Pressure
Inspiratory Resistance
Inspiratory Tidal Volume
Inspiratory Time
Intracranial Pressure
Diastolic Arterial lood Pressure
Mean Arterial Blood Pressure
Systolic Arterial Blood Pressure
% Leak in Tidal Volume (Insp/Exp)
Left Arterial Pressure

Ejection Fraction
Emboli 1
Emboli 2
Emboli 3
End Diastolic Volume
Line Pressure
Mean Airway Pressure
Mattress Temperature
Mattress Temperature Setting
Respiration Rate
Ventilation Mode
Myocardial Temperature
Nasopharyngeal Temperature
Nitric Oxide
Nitric Dioxide
Diastolic Cuff Blood Pressure
Mean Cuff Blood Pressure
Systolic Cuff Blood Pressure
Oxygen Consumption
Oxygen Extraction Index
Oral Temp
Arterial pCO2
Arterial pO2
Peak Flow
Plateau Time
Positive Pressure Duration
Potassium
Pressure Control
Pressure Limit
Pressure Sensitivity
Pressure Support
Pulmonary Capillary Wedge Pressure
Pulmonary Arterial Diastolic Pressure
Pulmonary Arterial Mean Pressure
Pulmonary Arterial Systolic Pressure
Pulse Amplitude
Pulse Rate
Pump Flow
Venous pCO2
Venous pO2
Rate Pressure Product
Rectal Temperature
Right Ventricular Ejection Fraction
Left Cardiac Work
Left Cardiac Word Index
Left Stroke Work
Left Stroke Work Index
Left Ventricular Ejection Time
Static Compliance
ST Interval
Stat Stroke Volume Index
Stat Stroke Volume Index
Venous SO2
Oxygenator Sweep
Systeolic Time Ratio
Thoracic Fluid Index
Tidal Volume Setting
Transcutaneous pCO2
Transcutaneous pO2
Tympanic Temperature
Venous pH
Venous Temperature
Volume Flow1
Volume Flow 2
Volume Flow 3
Water Temperature
Weight
CoHB
MetHB
Perfusion Index
O2 Delivery
FICO2
Amplitude
Amplitude 2
Mode
Inspired O2
Suppression Ratio
Insp Time Set
Low IP Set
PIP Set
Vent Rate Set
CPAP Set
Dose Mode
Dose Value
Flow Chk
History Cleared

Stat Right Ventricular Ejection Fraction
Arterial SO2
Set Point Temperature
Skin Temperature
Skin Temperature Setting
Pulse SO2 1
Pulse SO2 2
Spectral Edge Frequency
Spontaneous Respiration Rate
O2 Delivery
O2 Delivery Index
Stroke Volume
Stroke Volume Index
Stroke Volume Variation
Systemic Vasc Resistance
Systemic Vasc Resistance Idx
Inter beat interval
Heart rate variability
Baroreflex sensitivity
Total peripheral resistance
Total arterial compliance
Max. steepness of current upstroke
Ascending aortic impedance at DIA
Pulse Press Variation
Systolic Press Variation
Umbilical Artery Pressure Systolic
Umbilical Artery Pressure Diastolic
Umbilical Artery Pressure Mean
Abd Girth
Alveolar-Art
Amp Power
Art/Ven O2 Diff
Body Site
CRT
ETT Size
Gas Temp
Head Circ
Hertz
Length
Pain Scale
Pathologic Source
QP:QS
Sample Method

Infusion Mode
Label
Primary Rate
Pri Vol Infused
Vol Remaining
Secondary Rate
Sec Vol Infused
Time Remaining
Central Ven O2 Sat
Shunt/Tot Flow
Slope
Specimen Type
Taped At
Testing Lab
Vital Capacity

Compatible Devices

Atom Medical	Infra Warmer V505
Baxter Healthcare	AS 50
Baxter Healthcare	Colleague IP
Baxter Healthcare	FloGuard 6201
Baxter Healthcare	FloGuard 6301
Bird	VIP Gold/Sterling Ventilator
Cardiotronic	Aesculon Noninvasive Cardiac Output
Cardiotronic	ICON Hemodynamic Monitor
CDI	CDI 500 Bloodgas Monitor
Cincinnati Sub-Zero	Blanketrol II
Cincinnati Sub-Zero	Blanketrol III
Covidien	PB 840 Ventilator
Covidien	N200 Pulse Oximeter
Covidien	N295 Pulse Oximeter
Covidien	N395 Pulse Oximeter
Covidien	N595 Pulse Oximeter
Covidien	InfantStar 500 Ventilator
Covidien	InfantStar 950 Ventilator
Covidien	N600 Pulse Oximeter
Covidien	N600x Pulse Oximeter
Covidien	N85 EtCO2 Monitor
Covidien	N75 EtCO2 Monitor
Covidien	BIS VISTA (Complete Monitoring System)
Datex/Ohmeda	S/5 Patient Monitor
Draeger	Babylog 8000 Ventilator
Draeger	Babylog 8000SC Ventilator
Draeger	Evita Ventilator
Draeger	Evita 2 Ventilator
Draeger	Evita 4 Ventilator
Draeger	Infinity Patient Monitor
Draeger	SC7000
Draeger	SC8000
Draeger	SC9000XL
Edwards Life Sciences	Vigilance Hemodynamic Monitor
Edwards Life Sciences	Vigilance II Hemodynamic Monitor
GE	Dash 2000 Patient Monitor
GE	Dash 3000 Patient Monitor
GE	Dash 4000 Patient Monitor
GE	Solar 8000i Patient Monitor
GE	Solar 8000M Patient Monitor
IKARIA	INOvent NO Delivery

LiDCO	LiDCOrapid Hemodynamic Monitor
Maquet/Siemens	Servo 300 Ventilator
Maquet/Siemens	Servo i Ventilator
Maquet/Siemens	Maquet Perfusion Pump
Masimo	SET Radical-7 Pulse Oximeter
Masimo	SET Radical-9 Pulse Oximeter
Masimo	SET Radical-8 Pulse Oximeter
Mennen Medical	Horizon 2000 Patient Monitor
Philips	CMS 2001 Patient Monitor
Philips	V24 Patient Monitor
Philips	V26 Patient Monitor
Philips	MP5 Patient Monitor
Philips	MP20 Patient Monitor
Philips	MP40 Patient Monitor
Philips	MP50 Patient Monitor
Philips	MP60 Patient Monitor
Philips	MP70 Patient Monitor
Philips	MP80 Patient Monitor
Philips	MP90 Patient Monitor
Philips	Capnogard EtCO2 Monitor
Somanetics	INVOS 5100B Cerebral/Somatic Oximeter
Somanetics	INVOS 5100C Cerebral/Somatic Oximeter
Sorin	Sorin S3 Perfusion Pump System
Sorin	Sorin C5 Perfusion Pump System
Sorin	Sorin S5 Perfusion Pump System
Sorin	Sorin SIII Encore Perfusion Pump System
Spectrum Medical	Spectrum M2 Flow Meter
Spectrum Medical	Spectrum M3 Flow Meter
Transonic Systems	Transonic HT 109 Flow Meter
Viasys	Viasys Avea Ventilator
Welch-Allyn	Propaq Physiomonitor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 27, 2013

Covidien
c/o Ms. Kelsey Lee
Senior Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K123002
Trade/Device Names: Vital Sync™ System, Model 5000
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: MWI
Dated: January 31, 2013
Received: February 1, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123002

Device Name: Vital Sync™ System, Model 5000

Indications for Use:

The Vital Sync™ System is intended for the display and recording of multiple physiological parameters of adult, pediatric and neonatal patients. It is not intended for alarm notification, nor is it intended to control any of the independent bedside devices it is connected to.

The Vital Sync™ System displayed parameters are listed on the following pages.

WARNING: The Vital Sync™ System is not an active patient monitoring system. It is intended to supplement and not to replace any part of the hospital's device monitoring."

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Owen P. Faris -S

Vital Sync™ System Displayed Parameters

Amplitude Integrated EEG Left
Amplitude Integrated EEG Right
Anesthetic Agent
Air Temperature
Air Temperature Setting
Airway Temperature
Arterial Base Excess
Arterial Bicarbonate
Arterial pH
Arterial Temperature
Average Heart Rate
Axiallary Temp
Bi-Level Positive Airway Pressure
BIS
Bladder Temperature
Blood Temperature/Pulm. Artery Temperature
Body Surface Area
Bolus Cardiac Output
Bolus Cardiac Index
Brain PO2
Brain Temp
Calculated SO2
Cardiac index
Cardiac Output
Stat Cardic Index
Stat Cardic Output
Cardioplegia Line Pressure
Central Venous Pressure
Cerebral Perfusion Pressure
Cerebral Blood Flow
Ch1 rSO2
Ch2 rSO2
Ch3 rSO2
Contractility Index
Continuous Cardiac Index
Continuous Cardiac Output
Control Temp
Core Temperature
Coronary Sinus Pressure
Continuous Positive Airway Pressure
Delta Pressure
Dynamic Compliance
Ejection Fraction
Emboli 1
Emboli 2
Emboli 3
End Diastolic Volume
End Diastolic Volume Index
Stat End Diastolic Volume Index
Exhaled Minute
End Inspiratory Pressure
End Systolic Volume
End Systolic Volume Index
End Tidal CO2
Environmental Temperature
Esophageal Temperature
Exhaled Tidal Volume
Exhalation Time
Expired Positive Airway Pressure
Inspired Fraction of Oxygen
Infusate Temp
Flow Rate 1
Flow Rate 2
Flow Rate 3
Gastric pCO2
Heart Rate
Heater Output Percent
Heater Output Percent Setting
Hematocrit
Hemoglobin
High Inspired Pressure Setting
Humidity
Humidity Setting
Variation of Contractility Index
Inspired: Expired Ratio
Inspired CO2
Inspired O2 Setting
Insp Pos Air Pressure
Inspiratory Pressure
Inspiratory Resistance
Inspiratory Tidal Volume
Inspiratory Time
Intracranial Pressure
Diastolic Arterial Blood Pressure
Mean Arterial Blood Pressure
Systolic Arterial Blood Pressure
% Lead in Tidal Volume (Insp/Exp)
Left Arterial Pressure
Left Cardiac Work
Left Cardiac Work Index
Left Stroke Work
Left Stroke Work Index
Left Ventricular Ejection Time
Line Pressure
Mean Airway Pressure
Mattress Temperature
Mattress Temperature Setting
Respiration Rate
Ventilation Mode
Myocardial Temperature
Nasopharyngeal Temperature
Nitric Oxide
Nitric Dioxide
Diastolic Cuff Blood Pressure
Mean Cuff Blood Pressure
Systolic Cuff Blood Pressure
Oxygen Consumption
Oxygen Extraction Index
Oral Temp
Arterial pCO2
Arterial pO2
Peak Flow

Plateau Time
Positive Pressure Duration
Potassium
Pressure Control
Pressure Limit
Pressure Sensitivity
Pressure Support
Pulmonary Capillary Wedge Pressure
Pulmonary Arterial Diastolic Pressure
Pulmonary Arterial Mean Pressure
Pulmonary Arterial Systolic Pressure
Pulse Amplitude
Pulse Rate
Pump Flow
Venous pCO2
Venous pO2
Rate Pressure Product
Rectal Temperature
Right Ventricular Ejection Fraction
Stat Right Ventricular Ejection Fraction
Arterial SO2
Set Point Temperature
Skin Temperature
Pulse SO2 1
Pulse SO2 2
Spectral Edge Frequency
Spontaneous Respiration Rate
Static Compliance
St Interval
Stat Stroke Volume Index
Venous SO2
Oxygenator Sweep
Systolic Time Ratio
Thoracic Fluid Index
Tidal Volume Setting
Transcutaneous pCO2
Transcutaneous pO2
Tympanic Temperature
Venous pH
Venous Temperature
Volume Flow 1
Volume Flow 2
Volume Flow 3
Water Temperature
Weight
CoHB
MetHB
Perfusion Index
O2 Delivery
PICO2
Amplitude
Amplitude 2
Mode
Inspired O2
Supression Ratio
Insp Time Set
Low IP Set
PIP Set
Vent Rate Set
CPAP Set
Dose Mode
Dose Value
Flow Chk
History Cleared
Infusion Mode
Label
Primary Rate
Pri Vol Infused
Vol Remaining
Secondary Rate
Sec Vol Infused
Time Remaining
Central Ven O2 Sat
O2 Delivery Index
Stroke Volume
Stroke Volume Index
Stroke Volume Variation
Systemic Vasc Resistance
Systemic Vasc Resistance Idx
Inter Beat interval
Heart Rate Variability
Baroreflex Sensitivity
Total Peripheral Resistance
Total Arterial Compliance
Max. Steepness of Current Upstroke
Ascending Aortic Impendence at DIA
Pulse Press Variation
Systolic Press Variation
Umbilical Artery Systolic Pressure
Umbilical Artery Diastolic Pressure
Umbilical Artery Mean Pressure
Abd Girth
Alveolar-Art
Amp Power
Art/Ven O2 Diff
Body Site
CRT
ETT Size
Gas Temp
Head Circ
Hertz
Length
Pain Scale
Pathologic Source
QP:QS
Sample Method
Shunt/Tot Flow
Slope
Specimen Type
Taped At
Testing
Lab
Vital Capacity